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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Joseph Hermes Kaal

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2115

26774

7590

02/27/2009

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EXAMINER

DOUKAS, MARIA E

ART UNIT

PAPER NUMBER

3767

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,782	<b>Applicant(s)</b> KAAL ET AL.	
	<b>Examiner</b> MARIA E. DOUKAS	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/28/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 is listed as dependent on cancelled claim 12, and claim 14 depends from claim 13.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 7-11, 13, 16-22, and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,222,942 to Bader (Bader).

#### In Reference to Claims 1, 2, 5

A disabling system for a syringe (syringe 1) comprising a plunger (plunger rod 13) having two ratchets (serration 27) disposed longitudinally along the plunger (Figure 6) and a collar (stopping collar 19) mountable to a barrel (cylinder 2) of said syringe, said

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collar comprising an inner member (clamping tongue 41) and an outer member (check tongues 22) incapable of rotation relative to each other (col. 5, line 58 – col. 6, line 3, wherein since the tongue 41 is designed integrally with the collar 19, it will not be capable of rotating with respect to the outer member) having at least one pawl (catches 23) capable of engaging said ratchet (Figure 6), said inner member operable to prevent engagement of said ratchet by the pawl until the plunger is depressed (col. 5, line 58 – col. 6, line 9).

#### In Reference to Claims 3 and 4

The system of claim 2 (see rejection of claim 2 above), wherein each of said two opposed ratchets comprise a plurality of aligned teeth (teeth 28; Figure 6) and are alignable relative to two pawls (Figures 1-6) so as to prevent withdrawal of the plunger following plunger depression (col. 4, lines 46-55).

#### In Reference to Claims 7-9 and 13

A syringe (syringe 1) comprising a plunger (plunger rod 13) comprising two opposed ratchets (serration 27; Figures 1, 6), a barrel (cylinder 2) and a collar (collar 19) mountable to said barrel, said collar comprising an inner member (clamping tongue 41) and an outer member (check tongues 22) incapable of rotation relative to each other (col. 5, line 58 – col. 6, line 3, wherein since the tongue 41 is designed integrally with the collar 19, it will not be capable of rotating with respect to the outer member) having

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two pawls (catches 23; Figures 1-6), said inner member to prevent engagement of said ratchet by the pawl until the plunger is depressed (col. 5, line 58 – col. 6, line 9).

In Reference to Claims 10 and 11

The syringe of claim 9 (see rejection of claim 9 above) wherein said two opposed ratchets comprise a plurality of aligned teeth (teeth 28; Figure 6) and are alignable with the two pawls so as to prevent withdrawal of the plunger following plunger depression (col. 4, lines 46-55).

In Reference to Claims 16 and 17

A method of operating a syringe comprising: providing a syringe (syringe 1) comprising a plunger (plunger rod 13) having at least one ratchet (serration 27), a barrel (cylinder 2) and a collar (collar 19) mountable to the barrel, said collar comprises an inner member (clamping tongue 41) and an outer member (check tongues 22) having at least one pawl (catches 23; Figures 1-6); and depressing said plunger from a first position where the pawl is not engaged with the ratchet to a second position where they are engaged (col. 4, lines 7-60).

In Reference to Claims 18-22

A method of making a disabling system for a syringe comprising: forming at least two ratchets (serrations 27; Figure 6) comprising a plurality of aligned teeth (teeth 28) on a plunger (plunger rod 13); and positioning an inner member (clamping tongue 41) of a

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collar (collar 19) to prevent engagement of the ratchets with a pawl (catches 23) of the outer member (check tongues 22) until the plunger is depressed (col. 4, lines 7-60). Further having the inner member and outer member be incapable of rotation relative to each other (col. 5, line 58 – col. 6, line 3, wherein since the tongue 41 is designed integrally with the collar 19, it will not be capable of rotating with respect to the outer member).

#### In Reference to Claims 24-29

A method of making a syringe comprising: forming at least two ratchets (serrations 27; Figure 6) comprising a plurality of teeth (teeth 28) on a plunger (rod 13); mounting a collar (collar 19) comprising an inner member (clamping tongue 41) and outer member (check tongue 22) incapable of rotation relative to each other (col. 5, line 58 – col. 6, line 3, wherein since the tongue 41 is designed integrally with the collar 19, it will not be capable of rotating with respect to the outer member ), wherein the outer member has at least two pawls (catches 23); mounting the plunger for movement in the barrel with the inner member positioned to prevent engagement of the ratchets and pawls until the plunger is depressed (col. 4, lines 7-60; col. 5, line 58 – col. 6, line 9).

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6, 14, 15, 23, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,222,942 to Bader (Bader) in view of UK Patent Application No. GB 2203047 to Banks (Banks).

In Reference to Claims 6 and 14

Bader teaches the device of claims 5 and 13 (see rejection of claims 5 and 13 above) but fails to teach wherein the outer member comprises two fingers and the plunger comprises guide slots that engage. Banks teaches a syringe comprising a plunger 4 that has splines 7-10 that lock into guide channels 11-14 in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Bader to have guide channels on the plunger and splines on the collar outer member as taught by Banks in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6).

In Reference to Claim 15

Bader teaches a syringe (syringe 1) comprising: a barrel (cylinder 2) that comprises two pawls (catches 23); and a plunger (rod 13) comprising two opposed ratchets (serrations 23) that engage the pawls to prevent withdrawal of the plunger after plunger depression (col. 4, lines 46-55); and a collar (collar 19) having an inner member (clamping tongue 41) and outer member (check tongue 22) incapable of rotation relative

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to each other (col. 5, line 58 – col. 6, line 3, wherein since the tongue 41 is designed integrally with the collar 19, it will not be capable of rotating with respect to the outer member ), wherein the outer member has at least two pawls (catches 23); mounting the plunger for movement in the barrel with the inner member positioned to prevent engagement of the ratchets and pawls until the plunger is depressed (col. 4, lines 7-60; col. 5, line 58 – col. 6, line 9). Bader fails to teach wherein the outer member comprises two fingers and the plunger comprises guide slots that engage. Banks teaches a syringe comprising a plunger 4 that has splines 7-10 that lock into guide channels 11-14 in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Bader to have guide channels on the plunger and splines on the collar outer member as taught by Banks in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6).

#### In Reference to Claims 23 and 30

Bader teaches the method of claims 22 and 29 (see rejection of claims 22 and 29 above) but fails to teach wherein the outer member comprises two fingers and the plunger comprises guide slots that engage. Banks teaches a syringe comprising a plunger 4 that has splines 7-10 that lock into guide channels 11-14 in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6).



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It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Bader to have guide channels on the plunger and splines on the collar outer member as taught by Banks in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6).

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 7,331,934 (Suresh) teaches a syringe with a disabling mechanism. U.S. Patent No. 5,562,623 (Shonfeld) teaches a single-use syringe with a plunger that has a plurality of ratchet like teeth.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767